

REMARKS

Claims 1-31 and 33-38 are pending. By this Amendment, claims 5, 6, 11, 12, 32, 35, 39-64 are cancelled, claims 1, 3, 8, 9, 31, 33, 34, 36-38 are amended and no new claims are added.

Request for Telephone Interview Before Issuance of Next Office Action

Applicant requests that the Examiner contact Applicants counsel in this application to schedule a telephone interview to discuss the pending claims of this application before issuing an Office Action.

35 U.S.C. § 102

The Office Action rejected 1, 20, 28-30 and 33-35 under 35 U.S.C. § 102(b) as being anticipated by Swartz et al. (U.S. 5,800,413). By this Amendment, Applicant has amended claim 1 to recite the limitations: “further wherein a length from the primary curve to the secondary curve is between 14 cm and 17 cm, a length from the secondary curve to the catheter tip is between 3 cm and 8 cm; and further wherein an angle of the secondary curve is between 90 and 100 degrees from the shaft.”

These limitations were previously presented in claims 5, 6 and 12, which depend directly or indirectly from claim 1. The Office Action admits that these limitations are not disclosed or suggested by Swartz et al. Accordingly, claim 1 cannot be anticipated by Swartz et al., and should be patentable. Claims 2-4, 7-10 and 13-31 depend directly or indirectly from claim 1 and should be patentable for at least the same reasons as claim 1.

35 U.S.C. § 103

The Office Action rejected claims 2, 13-17, 23 and 26 under 35 U.S.C. § 103(a) as being unpatentable over Swartz in view of Parker (U.S. Patent 5,221,270). As indicated above, Applicant has amended claim 1 to include limitations not disclosed or suggested by the Swartz reference therefore making claim 1 patentable. Therefore, claims 2, 13-17, 23 and 26 should be patentable at least by the virtue of their dependency on a patentable base claim.

The Office Action rejected claims 3-12, 21-22, 24-25, 27 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Swartz et al. With regard to claims 3-9 and 24-25, the Office Action asserts that Swartz discloses the claimed invention except for disclosing the exact size specification of certain centimeter lengths of the catheter between curves and tip. The Office Action then cites the case of *In Re Rose* in support of this obviousness rejection and also asserts, without citing any references, “although Swartz does not explicitly disclose the specific dimensions, they all fall within the range of normal catheter micro catheter used in practice.” Applicant respectfully traverses the rejection, particularly with regard to limitations of claims 5 and 6.

Applicant respectfully traverses the rejection. MPEP § 2144 III states “legal precedent can provide the rational supporting obviousness only if the facts in the case are sufficiently similar to those in the application.” Here, the facts of *In Re Rose* are not similar to the facts in the present application. *In Re Rose* involves a patent claim where the only distinction between the prior art and the claimed invention was the size of a lumber bundle. In the prior art it was well known to make lumber bundles of a size that could be handled by individuals. In *In Re Rose* the claimed invention was a lumber bundle large enough to require a forklift to move the

lumber bundle. The holding of *In Re Rose* was that this difference in size did not rise to the level of patentability. The device in question here is a catheter for use within the living human body. The invention claimed is nothing so crude and imprecise as a bundle of lumber to be handled by a forklift. Catheters must be precisely formed to prevent damage to the living person into whom they are introduced. Further, the dimensions claimed do not represent a mere change in size that is addressed in *In Re Rose*. As the applicant has previously discussed, the particular dimensions claimed have been found by the Applicant to facilitate the accomplishment of a medical procedure with a reduction in the number of medical devices that are introduced into the patient's body thus reducing trauma, risk and invasiveness of the procedure. Accordingly, the facts of this application are very different than those present in the cited case. Therefore, Applicant takes the position that the facts of *In Re Rose* are not sufficiently similar to the present application to support a rejection for obviousness of the claimed limitations.

Second, here, as has previously been discussed in the Response filed July 28, 2009, the invention relates to a catheter adapted to provide access to both contralateral and ipsilateral visceral arteries from a single access point in one of the femoral arteries. The particular dimensions recited in the claims have been discovered by the inventor to be particularly adapted to providing access to these arteries with a single catheter, thus eliminating the need for an interventional radiologist to use several catheters to provide access to these same visceral arteries. The present invention, as demonstrated by the evidence submitted with the Amendment filed July 28, 2009, provides unique and unexpected benefits which represent a surprising result to those of ordinary skill in the art. The invention, as presently claimed, should be patentable for this additional reason.

Third, recently, the Supreme Court stated in *KSR v. Teleflex*, that “rejections on obviousness cannot be sustained with mere conclusory statements: Instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Here, the Office Action has not presented a *prima facie* case of obviousness, because there is no reasoning articulated and there is no rational underpinning presented other than to cite to *In Re Rose*, to acknowledge that Swartz does not disclose these specific dimensions and to state that “the dimensions all fall within the range of normal catheter and microcatheters used in practice” without any reference to prior art to support this assertion. For these reasons the Office Action does not establish a *prima facie* case of obviousness. Accordingly, claim 1 as amended should be patentable over the prior art of record in the present application for this reason as well.

With regard to claims 10-12, the Office Action indicates that it would have been obvious to one having ordinary skill in the art at the time of the invention, to make a catheter with the limitations of claims 10-12, and the Office Action cites to *In Re Aller* indicating that discovering optimum of workable ranges involves only routine skilled in the art. Claims 11 and 12 have been cancelled and their limitations incorporated into independent claim 1. The holding of *In Re Aller* applies only for ranges which are known to be result effective variables. According to MPEP 2144.05, “a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that

treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.) See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy.) Here, the Office Action has not presented any evidence that the claimed dimensions are known in the prior art to be result effective variables. Thus, the Office Action does not establish a *prima face* case of obviousness. Accordingly, Applicant respectfully submits that claim 1 (now incorporating the limitations of claims 11 and 12) and 10 are patentable for at least this additional reason.

With regard to claims 21-22 and 24, the Office Action again rejects these claims as obvious and cites *In Re Rose*. Applicant has addressed this rejection in detail above with relation to the rejections of claims 5 and 6. As discussed with relation to claims 5 and 6, the facts of *In Re Rose* are not sufficiently similar to the facts of the present application to support a rejection of claims 21-22 and 24 as obvious. Claims 21-22 and 24 should be patentable for at least this additional reason.

With regard to claims 27 and 36-38, first, these claims are patentable by virtue of their dependency on a patentable base claim, second, the obviousness rejection citing *Newin v. Erlichman*, indicates “it would have been obvious to one having ordinary skill in the art at the time that the invention was made to form the straighter tapered end section and second tapered section separately removable since it has been held that constructing a formally integral structure and various elements involves only routine skill in the art.” Applicant respectfully traverses the rejection in that the Examiner has not presented any evidence that it is known in the prior art to make these structures integral. Accordingly reliance on *Newin v. Erlichman* is misplaced and

claims 27 and 36-38 should be patentable for this additional reason. Applicant respectfully requests that the Examiner withdraw the rejection.

With regard to claim 31, the Office Action states that “it would have been obvious to one having ordinary skill in the art at the time the invention was made, to make a catheter from germ retarding materials since it has been held to be within a general skill worker in the art, to select the known material on the basis of suitable for the intended purpose.” As discussed above, these claims are patentable at least by virtue of their dependency on a patentable base claim.

35 U.S.C. § 112

The Office Action rejected claim 1 under 35 U.S.C. § 112, second paragraph, as being indefinite. Particularly, the Office Action indicated that there was insufficient antecedent basis for the limitation “the first curve.” By this Amendment, Applicant has amended the claims to consistently recite “the primary curve.” Applicant respectfully requests that the Examiner withdraw the rejection.

The Office Action rejected claims 3, 8, 33, 34, 35, 36, 37 and 38 under 35 U.S.C. § 112, as being indefinite with regard to antecedent basis for the term “the second tapered section”. Applicant has amended the claims to provide antecedent basis for this term. Applicant respectfully requests that the Examiner withdraw the rejection.

The Office Action also rejected claims 11 and 35 as being indefinite. Applicant has canceled claims 11 and 35 without prejudice or disclaimer in order to advance prosecution. Applicant respectfully requests that the Examiner withdraw the rejection.

Drawings

The Office Action objected to the drawings under 37 C.F.R. 1.83(a) indicating that the drawings must show every feature of the invention specified in the claims. In particular, the Office Action indicating that the primary curve being equal to 360° must be shown in the drawings. By this Amendment, to advance prosecution, Applicant has canceled claim 11 reciting this limitation without prejudice or disclaimer. Applicant respectfully requests that the Examiner withdraw the objection.

Amendments made herein are made without prejudice or disclaimer. Applicant reserves the right to prosecute the same or similar claims in future continuation applications.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. C. Onderick', with a long horizontal flourish extending to the right.

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